(i) Must be disposed of in a manner that protects against the contamination of other food; or

(ii) If the adulterated food is capable of being reconditioned, it must be:

(A) Reconditioned (if appropriate) using a method that has been proven to be effective; or

(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with §117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

§ 117.95 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

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§ 117.110 Defect action levels.

(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at*http://www.fda.gov/pchfrule* and at*http://www.fda.gov*.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 Food safety plan.

(a) *Requirement for a food safety plan.* (1) You must prepare, or have prepared, and implement a written food safety plan.

(2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(b) *Contents of a food safety plan.* The written food safety plan must include:

(1) The written hazard analysis as required by § 117.130(a)(2);

(2) The written preventive controls as required by § 117.135(b);

(3) The written supply-chain program as required by subpart G of this part;

(4) The written recall plan as required by § 117.139(a); and

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);

(6) The written corrective action procedures as required by § 117.150(a)(1); and

(7) The written verification procedures as required by § 117.165(b).

(c) *Records.* The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 117.130 Hazard analysis.

(a) *Requirement for a hazard analysis.* (1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.

(2) The hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.